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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,998	10/16/2003	Patrick J. Sweeney	029815-0103	7428

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FOLEY & LARDNER LLP
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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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08/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/686,998

Applicant(s)

SWEENEY, PATRICK J.

Examiner

Cheryl Miller

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 10,12,18,22,28,37,43 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-9, 11, 13, 15, 17, 21, 23, 25, 27, 29, 30, 32, 34, 36, 38, 39, 41, 61-65, 68, and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08).
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,3,5-13,15,17,18,21-23,25,27-30,32,34,36-39,41,43,61,63-66 and 68-70.

DETAILED ACTION***Response to Arguments***

Applicant's arguments filed June 12, 2007 have been fully considered but they are not persuasive. The applicant has argued that Rabbe et al. (US 6,344,057) does not disclose artificial discs. The examiner disagrees. First, no structure has been claimed here. The claim limitation only recites intended use language, some part that is for replacing a natural disc. Rabbe's implant is disclosed to replace both a vertebral body and two adjacent discs. See figures 1 and 2, wherein V3, D2, and D3 are removed for insertion of implant (col.8, lines 49-67; col.3, lines 42-57; implant disclosed to attach to adjacent endplates therefore, discs are inherently removed). Because portions of Rabbe's implant system (caps 23 considered the artificial discs) are positioned where the discs were once located, they are replacing the natural discs and may be called "artificial discs". The applicant has argued that Rabbe's components 23 do not provide motion or articulation but instead provide fusion. However, the applicant's claims do not require motion or articulation or even bearing surfaces. In fact, no structure of applicant's discs has even been claimed. The only limitation claimed is an "artificial disc", and a component of Rabbe that replaces the natural disc is being considered an "artificial disc" since it is intended for placement where the disc was once located.

The applicant has also argued that Rabbe does not disclose a pedicle screw retainer. The examiner disagrees. The examiner is considering 57 or 107 to be a "pedicle screw retainer". No structure is associated with this limitation either. All that is required by the claim is a retainer (thing capable of housing) capable of housing a pedicle screw. A screw need not even be present. Only a retainer that has room to accommodate a screw and is adapted for attachment to

Art Unit: 3738

a pedicle. Rabbe's structures 57 and 107 are both retainers in that they have openings for accommodating screws. Further, "pedicle" is intended use language, that is a screw for placement in a pedicle. Rabbe's structures 57 and 107 are *capable of housing screws* and is *adapted for attachment to a pedicle*.

The applicant has argued that Strnad et al. (US 6,296,665 B1) does not disclose an artificial disc. The examiner disagrees. No structure has been claimed here. The claim limitation only recites intended use language, some part that is for replacing a natural disc. Strnad's implant is disclosed to replace both a vertebral body and two adjacent discs (col.5, lines 45-50). Because portions of Strnad's implant system (bone graft material) are positioned where the discs were once located, they are replacing the natural discs and may be called "artificial discs". The applicant has argued that Strnad's components do not provide motion or articulation but instead provide fusion. However, the applicant's claims do not require motion or articulation or even bearing surfaces. In fact, no structure of applicant's discs has even been claimed. The only limitation claimed is an "artificial disc", and a component of Strnad that replaces the natural disc is being considered an "artificial disc" since it is intended for placement where the disc was once located.

The applicant has also argued that Strnad does not disclose a pedicle screw retainer. The examiner disagrees. The examiner is considering 202 to be a "pedicle screw retainer". No structure is associated with this limitation either. All that is required by the claim is a retainer (thing capable of housing) capable of housing a pedicle screw. A screw need not even be present. Only a retainer that has room to accommodate a screw and is adapted for attachment to a pedicle. Rabbe's structures 202 are both retainers in that they have openings for

Art Unit: 3738

accommodating screws (see fig.8a, 8b). Further, "pedicle" is intended us language, that is a screw for placement in a pedicle. Strnad's structures 202 are *capable of housing screws* and are *adapted for attachment to a pedicle*.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-9, 11, 13, 15, 17, 21, 23, 25, 27, 29, 30, 32, 34, 36, 38, 39, 41, 61-63, 68, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Rabbe et al. (US 6,344,057 B1, cited in IDS). Rabbe discloses a system comprising a support or shaft (21), first and second endplates (22 or 83), two artificial disc implants (23, located where the natural disc are removed therefore, are replacing the discs) attached to the endplates (see fig.3), and a pedicle screw retainer (57 in fig.3 or 107 in fig.9) having a top (superior thickness), bottom (inferior thickness) and side (plate length surface) with aperture having screws (108, 5) *adapted* to fit through a pedicle. Rabbe disclose the shaft/support to be adjustable (by threads 32) and the endplates to screw onto the shaft/support (by threads 32/41).

Claims 1, 3, 5-9, 21, 23, 25, 27, 29, 30, 32, 34, 36, 38, 39, 61-65, and 68-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Strnad et al. (US 6,296,665 B1, cited previously). Strnard discloses a system comprising a support or shaft (102), first and second endplates (18, 20), an artificial disc implant (bone graft material, disclosed to replace both the vertebral body and two discs, therefore, it may be considered a disc replacement; fig.8b, col.5, lines 45-48;

Art Unit: 3738

col.6, lines 22-24, 36-40) attached to the endplates, and a pedicle screw retainer (202) having a top (superior thickness), bottom (inferior thickness) and side (plate length surface) with aperture (204) having screws (col.6, lines 12-15) *adapted* to fit through a pedicle. Strnard disclose the shaft/support to be adjustable (see fig.8a, 8b, 9).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

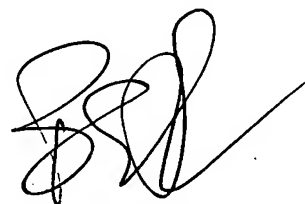
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER